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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/493,601	01/28/2000	Edward A Dennis	UCSD0-078-2	2450

7590 10/04/2005

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EXAMINER

SAIDHA, TEKCHAND

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 10/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/493,601	<b>Applicant(s)</b> DENNIS ET AL.	
	<b>Examiner</b> Tekchand Saidha	<b>Art Unit</b> 1652	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 October 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-9 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

*U*

*Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-2, drawn to a cDNA segment of 690?? [Figure 1 or SEQ ID NO: 3, as per the amendment to specification filed 10.4.2004] nucleotides from position 48?? to position 741 encoding a lysophospholipid-specific human brain lysophospholipase [Figure 1, or SEQ ID NO: 2 as per the amendment to specification filed 10.4.2004], classified in class 536, subclass 23.2.
- II. Claims 3-4, drawn to lysophospholipid-specific human brain lysophospholipase [Figure 1, or SEQ ID NO: 2 as per the amendment to specification filed 10.4.2004], classified in class 435, subclass 198.
- III. Claims 5-6, drawn to a method of inhibiting the catalytic activity of a recombinant lysophospholipid-specific human brain lysophospholipase by exposing the lysophospholipase enzyme to a solution containing methyl arachidonyl fluorophosphates, classified in class 435, subclass 18.
- IV. Claims 7-8, drawn to a method of treating a patient against diseases caused by increased levels of lysophospholipase by supplying a recombinant lysophospholipase enzyme, classified in class 424, subclass 94.6.
- V. Claims 9, drawn to a method of treating a patient against diseases caused by increased levels of lysophospholipase by supplying a recombinant lysophospholipase enzyme by 'gene augmentation therapy', classified in class 514, subclass 44.

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2. The inventions are distinct, each from the other because of the following reasons:

The DNA of group I is related to the lysophospholipase of group II by virtue of the fact that the DNA codes for the protein. The DNA molecule has utility for the recombinant production of the protein in a host cell. Although the DNA and the protein are related, since the DNA encodes the specifically claimed protein, they are distinct inventions because the protein product can be made by other and materially distinct processes, such as purification from the natural source. Further, DNA can be used for processes other than the production of protein, such as nucleic acid hybridization assays.

The DNA of group I is related to the method of using the protein of group III & IV by virtue of the fact that the protein is encoded by the DNA. The inventions are distinct, however because the DNA is not used in the method of treating and is not necessary for the method of treating. Therefore, the inventions are distinct.

Inventions I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the lysophospholipase encoding nucleic acid molecules, as claimed in Group I, can be used in a materially different process other than the methods of 'gene augmentation therapy' of Group V, such as use of the nucleic acids in a method to produce recombinant lysophospholipase protein. Inventions II and V are similarly distinct.

Inventions II and III or II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the lysophospholipase molecules, as claimed in Group II, can be used in a materially different process other than the methods of ' inhibiting the activity of lysophospholipase of Group III or treating patient of group IV, such as use of the lysophospholipase protein for making antibodies.

The methods of Inventions III, IV and V are related in that each method requires the use of I or II. However, the steps and end points of the methods are wholly different and therefore Inventions III, IV and V are patentably distinct.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

3. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).


5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tekchand Saidha whose telephone

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number is (571) 272 0940. The examiner can normally be reached on 8.30 am - 5.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (571) 272 0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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September 29, 2005